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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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LAW OFFICES OF KHALILIAN SIRA, LLC			BOESEN, AGNIESZKA	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/727,335	Applicant(s) HAMMOND ET AL.	
	Examiner Agnieszka Boesen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 9, 13, 14 and 20-42 is/are pending in the application.  
4a) Of the above claim(s) 20-37, 40, and 41 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 14 and 42 is/are allowed.
- 6) ☒ Claim(s) 1-4, and 38 is/are rejected.
- 7) ☒ Claim(s) 9 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The Amendment filed March 20, 2007 in response to the Office Action of November 9, 2006 is acknowledged and has been entered. Claims 1, 2, 13, 14, 20, 28, and 36 have been amended. Claims 5-8, 10-12, and 15-19 have been canceled, and new claims 38-42 have been added. Claims 40 and 41 are withdrawn because they are drawn to a non-elected invention. Claims 1, 2, 13, 14, 38, 39, and 42 are currently examined.

#### ***Election/Restrictions***

Applicant's request for withdrawal of restriction requirement has been considered. However claims 20-37 will not be rejoined because no claims are indicated allowable at the present time.

#### ***Claim Objections***

Objection of claims 1-4, 9, 13, and 14 because of informalities is withdrawn in view of Applicant's arguments.

#### ***Claim Rejections - 35 USC § 101***

Rejection of claims 1-4, 9, 13, and 14 under 35 U.S.C. 101 is **withdrawn** in view of Applicant's amendment.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptide ligands, does not reasonably provide enablement for any ligands **is maintained. This rejection is now applied to new claim 39, drawn to the same subject matter.**

Applicants amended the claims to recite "isolated prion protein peptide ligands". The specification discloses peptide ligands of SEQ ID NOs: 44-212. Example 2, Figures 2 and 4, and Tables 10A and 10B disclose that some peptide ligands such as for example SEQ ID NOs: 154, 155, 157, 184-187, 189-194, and 197, 198, 199, 206, bind prion proteins with strong affinity while peptide ligands of SEQ ID NOs: 174-183, and 188 bind prion protein weakly. It is well recognized in the art that alterations in peptide's binding region, of for example an antibody CDRs, can abrogate the binding of an antibody to the antigen (see Li et al., 2000, Biochemistry, Vol. 39, p. 6296-6309). The presence of particular amino acid residues within a ligand is critical for the ligand's binding affinity to the antigen. Thus the ordinary artisan would immediately conclude that not all possible peptide ligands would bind prion protein. The current claims require that the prion-binding peptide ligand should be capable of binding to a peptide having an amino acid sequence of SEQ ID NO: 221. The claims broadly recite prion-binding peptide ligands. As discussed above applicant's disclosure is not commensurate in scope with the present claims. One would be unable to practice the current invention using any type of peptide ligand, because only specific peptide ligands have the capability of binding to prion proteins. For this reason the rejection is maintained.

#### New Rejection

**Claims 1-4, and new claim 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to prion binding peptide ligands capable of binding to a peptide having an amino acid sequence RYPxQ, wherein x is G, P, or N. In support of these claims, the application has identified a number of peptide ligands such as SEQ ID NOs: 44-212. However while the claims recite the expected function of peptide ligands, such as binding to peptide having an amino acid sequence RYPxQ, the claims do not identify a structure shared by the claimed peptide ligands. The claimed peptide ligands have not been sufficiently described in terms of their structure and function.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the specification discloses sequences of particular peptide ligands that bind prion proteins. However the claims are broadly drawn to any peptide ligands that must bind prion proteins. Applicant's claims pertain to a function of a compound that has an unknown structure. Claiming a product based on function does not provide sufficient description of the product as claimed. It has been well known that minor structural differences even among structurally related compounds or compositions can

result in substantially different biological activities. Therefore, structurally unrelated “molecules” encompassed by the claimed invention would be expected to have greater differences in their structural and functional characteristics and attributes

The mere contemplation of the claimed genus in the specification is not sufficient to support the presently claimed invention directed to a genus of compounds that inhibit the anti-apoptotic activity of Survivin. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which are not conventional in the art as of applicant's effective filing date. Claiming a genus of compounds that must possess the biological properties as contemplated by applicants' disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997). Possession may be shown by actual reduction to practice (provided in the specification and/or the 37 U.S.C. 1.132 declaration), clear description of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of compounds that are contemplated in the invention. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures disclosed in the as-filed specification. Thus, in view of the reasons

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set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Hardt et al. (J. Comp. Pathology, 2000) is **withdrawn** in view of Applicants amendment. However, in view of newly found prior art new rejection is made.

**Claims 1, 2, and new claim 39 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Chesebro et al. (US Patent 6,355,610 B2).**

Claims are drawn to a prion binding peptide ligand capable of binding to a peptide of an amino acid sequence RYPxQ, wherein x is G, P, or N.

Chesebro discloses peptides and peptide ligands binding to an amino acid sequence comprising RYPxQ, wherein x is G, thus RYPGQ (or Arg Tyr Pro Gly Gln) (see column 3, lines 18-57, column 7, lines 35-54, Example 11, particularly line 14, and SEQ ID NO: 18-22).

Thus by this disclosure Chesebro anticipates the current claims.

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***Claim Objections***

Claims 9 and 38 are objected to for depending from rejected claim 1.

***Conclusion***

Claims 4, 9, 13, 14, 38, and 42 are free of prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035.

The examiner can normally be reached on Monday through Friday 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**AB**

Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 5-29-2007  
Primary Examiner, TC1600